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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,583	03/28/2001	Hiroshi Tonoike	OKA-0025	3656

7590

09/11/2002

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EXAMINER

KIM, YOUNG J

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 09/11/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/818,583

Applicant(s)

TONOIKE, HIROSHI

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 2/28/01
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

The Group and/or Art Unit location of your application in the PTO has been assigned to Art Unit 1637. All further correspondence regarding this application should be directed to Group Art Unit 1637.

#### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### ***Specification***

Although Applicants have complied with the Sequence Rules by submitting a CRF (Computer Readable Format) and a paper copy of the Sequence Listing, the specification is objected to because on page 12, the nucleotide sequences have not been identified with their corresponding SEQ ID Numbers. It appears that the nucleotide sequence identified by GH20 is SEQ ID Number 1 and the nucleotide sequence identified by GH21 is SEQ ID Number 2. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Steiner et al.

(Nucleic Acids Research, 1995, vol. 23, no. 13, pages 2569-2570).

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Claims 1-6 are drawn to a method of amplifying nucleic acid from living body-derived sample wherein ionic surfactant is used (i.e., SDS or SARKOSYL).

Steiner et al. disclose a method of preparing a nucleic acid extraction method wherein said extraction employs an anionic surfactant sodium lauryl sarkosyl (limitation of claims 2-5) and the resulting solution is directly used in a polymerase chain reaction (limitation of claim 1). The extraction method disclosed by Steiner et al. employs 1% of the sodium lauryl sarkosyl (limitation of claim 6).

Therefore, Steiner et al. anticipates the invention as claimed.

Claims 1 and 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Burckhardt (U.S. Patent 5,501,963, March 26, 1996).

Claims 1 and 7-11 are drawn to a method of amplifying nucleic acid from a living body-derived sample (i.e., blood) wherein non-ionic surfactant is used (i.e., Tween).

Burckhardt discloses a method of amplifying nucleic acids from blood sample (limitation of claims 1 and 11) wherein a reaction solution comprises a non-ionic surfactant (limitation of claim 7), or one or more non-ionic surfactant (limitation of claim 8), Triton X-100 or Tween 20 (Abstract; column 5, lines 1-31; column 10, line 8). The reaction solution is disclosed as having 0.5% Tween 20 (limitation of claim 10).

Therefore, Burckhardt anticipates the invention as claimed.

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Liu et al. (Di-San Junyi Daxue Xuebao, 1999, vol. 21, no. 1, Abstract only).

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Claim 12 is drawn to a method of sample storage which comprises a living body-derived sample and storing the homogenized sample.

Liu et al. disclose a method of blood sample preparation (therefore, a living body-derived sample) wherein said blood sample is mixed with SDS-EDTA (therefore, homogenized), and stored at room temperature (therefore, method of storing).

Therefore, Liu et al. anticipate the invention as claimed.

No claims are allowed.

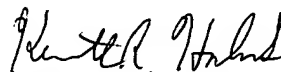
### *Inquiries*

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

9/6/02



  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

9/9/02